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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/773,121
Filing Date: February 05, 2004
Appellant(s): HARRIS ET AL.

Daniel T. Lund
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 8, 2007 appealing from the Office action mailed March 6, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,847,849	Mamo et al.
6,146,371	DeWindt et al.
5,255,691	Otten

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-22 and 24-50 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo et al. (US Patent Publication 20020147485 A1) in view of DeWindt et al. (US 6,146,371). Mamo et al. discloses a dilator with a conical distal tip and sheath as depicted in figures 8a-8c, in addition to a needle and a guide wire for application of neurostimulation therapy. "The needle is adapted to be withdrawn over the guide wire, and the dilator is adapted to be inserted over the guide wire proximal end to locate the guide wire within the dilator body lumen and to be advanced distally over the guide wire through the insertion path to dilate the insertion path to the dilator diameter" (page 2, paragraph 10). The process is displayed in figure 9a.

In addition, figure 9b "shows inserting and guiding a needle 36, e.g., a foramen needle 36, comprising a hollow needle body and a stylet or obdurator 40 within the needle body lumen, to the sacral nerve site in accordance with steps 50 and 52"(page 7, paragraph 98).

"The dilator body 47 is preferably conductive, and the dilator sheath 49 is preferably non-conductive but may bear radiopaque and visually observable depth marks 51 along its length to facilitate radiographic imaging when it is extended into the patient's body" (page 6, paragraph 91).

"The dilators 42 can be metal or plastic" (page 4, paragraph 74). Since the dilator, which includes both the dilator body and dilator sheath, can be constructed from plastic, the sheath and dilator are both deformable. In addition, according to Columbia University Press Dictionary, polyethylene is a "widely used plastic". Therefore, since the dilator can be constructed from a plastic, it would have been obvious to create the dilator from polyethylene.

Mamo et al. discloses the claimed invention except for the oblong cross-section. DeWindt et al. (US 6,146,371) discloses an oval-shaped cardiac cannula, for the purpose of utilizing the space of the percutaneous aperture efficiently, thereby minimizing the necessary size of the access aperture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the dilator, dilator sheath and needle as taught by Mamo et al. with the oblong or oval cross-section as taught by DeWindt et al., in order to provide the predictable results of utilizing the available space more efficiently than the traditional round cannula.

The modified Mamo et al. discloses the claimed invention except for the specific values of the width and height of the sheath and dilator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the sheath and dilator, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233 (see MPEP 2144.05).

2. Claim 23 stands rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Mamo et al., as applied to claims 1-22 and 24-45 above, in further view of Otten (US 5,255, 691). The modified Mamo et al. discloses the claimed invention except for the Tuohy needle. Otten teaches that it is known to utilize a Tuohy, for the purpose of accessing the epidural space of the spinal column. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the needle as taught by the modified Mamo et al. with the Tuohy needle as taught by Otten, since it was known in the art to utilize Tuohy needles for introducing a guide wire or stylet into the body.

(10) Response to Argument

The Appellant argues that "the references applied in the rejections under 35 U.S.C 103 fail to discloses or suggest an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section."

However, the examiner respectfully disagrees. Mamo et al. (US 6,847,849) discloses the claimed invention except for the oblong cross-section. DeWindt et al. teaches "a cannula which is oval-shaped in cross section and therefore ideally suited for

use in minimally invasive surgical procedures" (DeWindt et al., col. 1, lines 9-11). Since the oval shape is "ideally suited for use in minimally invasive surgical procedures" (DeWindt et al., col. 1, lines 10-11) it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the minimally invasive apparatus (the dilator, dilator sheath and needle) with the geometry (an oval cross section) as disclosed by DeWindt et al. since oval cross section "is one such modification which assists the surgeons in achieving the goal of minimizing the wound size for a variety of surgical procedures" (DeWindt et al., col. 6, lines 3-5).

Furthermore, in response to Appellant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as described above, both systems disclose minimally invasive surgical tools, wherein the non-circular or oval cross section is preferred in order to reduce wound size.

Additionally the Appellant argues that the plastic material as disclosed by Mamo et al. is not "substantially deformable". Furthermore, the Appellant contends that not all plastics are deformable such as that of a ballpoint pen (see page 3). The Appellant is reminded, however, that the claim limitation is recited as "substantially deformable". Therefore, since a ballpoint pen can be flexed, prior to its fracture, it is "substantially"

deformable. Therefore, since plastics can have an element of rigidity, yet still be "substantially" deformable, the plastic as discloses by Mamo et al. remains considered by the examiner as "substantially" deformable.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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TQAS TC 3700